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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,434	12/06/2003	John F. Kalafut	VI/02-022	8371
21140	7590	06/07/2005	EXAMINER	
GREGORY L BRADLEY MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051			ROY, BAISAKHI	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/729,434

Applicant(s)

KALAFUT ET AL.

Examiner

Baisakhi Roy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 25, 26, 28, 52, 53 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24, 27, 29-51, 54 and 56-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/30/04.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 5/11/05.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The previous restriction requirement has been withdrawn.

#### ***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species drawn to vessel visualization device implemented as a simple magnifying glass.

Species drawn to vessel visualization device implemented as a lamp.

Species drawn to vessel visualization device embodied as an infrared sensor.

Species drawn to vessel visualization device embodied as a small ultrasound imager.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with James Stevenson on 5/9/05 a provisional election was made with traverse to prosecute the invention of the infrared sensor, claims 1-24, 27, 29-51, 54, and 56-72. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25, 26, 28, 52, and 55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Double Patenting***

3. Applicant is advised that should claims 5-9 be found allowable, claims 11-15 will be objected to, respectively under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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4. Applicant is advised that should claim 10 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

5. Applicant is advised that should claims 34-38 be found allowable, claims 40-44 will be objected to, respectively under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

6. Applicant is advised that should claim 39 be found allowable, claim 45 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 33-45, 47, 51, 57, 63, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Iliia (6463309). Iliia discloses an apparatus for accessing a vasculature of a patient (abstract) with said apparatus comprising a limb support table mountable for supporting the limb of the patient (col. 3 lines 55-56, col. 5 lines 40-43), a vessel visualization device (col. 3 lines 48-55), a mounting system or frame enclosure for mounting said limb support table and said vessel visualization device positioned adjustably with respect to the patient with mechanism to be able to move the light source over a range of positions (col. 5 lines 18-39, col. 6 lines 63-67, col. 7 lines 1-20). Iliia teaches said limb support structure to comprise a brace or holding means

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detachably attachable to a top surface of the limb support table comprising straps and with said support or holding means made of disposable material such as foam and said vessel visualization structure comprising light source and clear or transparent window or surface to enable limb to be visible or backlit (col. 5 lines 40-67, col. 8 lines 8-10), and said apparatus also comprising a handgrip or limb support mechanism (col. 5 lines 35-39, col. 8 lines 8-10). The reference teaches the use of an optically-guided system for guiding and proper positioning of the needle for proper venipuncture (col. 3 lines 48-52, col. 6 lines 33-43) and heat lamp associated with the limb support structure (col. 6 lines 52-56). It further teaches said apparatus to comprise a power supply for providing electrical power to the apparatus (col. 5 lines 61-64).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 18-24, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines (6017307) in view of Zerhusen et al. (2003/0052787). Raines discloses an apparatus for accessing the vasculature of a patient with said apparatus comprising a pedestal with a base and structural member attached to the base (col. 8 lines 17-33), a table to support a limb associated with said pedestal (col. 4 lines 35-38), a storage device comprising channels or compartments incorporated underneath, tray,

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racks and drawers of various sizes attached to the pedestal (col. 4 lines 56-62, col. 8 lines 17-33). Raines also teaches a vessel visualization device associated with the pedestal and limb support table (col. 4 lines 34-38). Raines further teaches a power supply source (col. 10 lines 21-24). Raines however does not teach said vessel visualization device to include a mobility means. In a similar field of endeavor, Zerhusen et al. disclose a diagnostic system capable of imaging the limbs ([0188]) with mobility means such as wheels ([0107]). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Zerhusen et al. to modify the teaching by Raines for the purpose of providing mobility to the vessel visualization apparatus.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al. as set forth above, and further in view of Peterson et al. (4828208). Raines does not teach a mobility mechanism in the form of air cushion for the pedestal. Peterson et al. disclose a table used in medical settings with a pedestal-type base with various forms of mobility including an air cushion system (col. 6 lines 58-68). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Peterson et al. to modify the teaching by Raines and Zerhusen et al. for the purpose of providing mobility to the pedestal associated with the limb support table.

6. Claims 5-16, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al. as set forth above, and further in view of Ilia. Raines teaches conducting vascular examination on the arms or legs placed on the limb support table but does not teach attaching said limb to the support table. In the same field of endeavor, Ilia teaches said limb support structure to comprise a brace or holding



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means detachably attachable to a top surface of the limb support table comprising straps and with said support or holding means made of disposable material such as foam and said vessel visualization structure comprising light source and clear or transparent window or surface to enable limb to be visible or backlit (col. 5 lines 40-67, col. 8 lines 8-10), and said apparatus also comprising a handgrip or limb support mechanism (col. 5 lines 35-39, col. 8 lines 8-10). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Ilia to modify the teaching by Raines and Zerhusen et al. for the purpose of securing the limb to the support table and limit movement of the limb.

7. Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al as set forth above, and further in view of Svetliza (6178340). Raines teaches the use of various vessel visualization devices but does not teach said visualization device to be an infrared imager and also does not explicitly teach guiding the position of a needle into a vessel. In the same field of endeavor, Svetliza discloses an infrared based vessel visualization device (col. 3 lines 3-9) and guiding a needle for puncture into a desire vessel. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Svetliza to modify the teaching by Raines and Zerhusen et al. for the purpose of providing a more detailed or in depth visualization of the vessels.

8. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Zerhusen et al. Ilia does not explicitly teach the mechanism by which the limb support is attached to the table or the chair for the patient. Zerhusen et al.

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teach a limb imaging system where patient rests on a bed or chair with articulating arms extending to a table, chair, or other objects commonly found in healthcare settings ([0129] [0178]). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Zerhusen et al. to modify the teaching by Ilia for the purpose of facilitating better access to desired parts of the patient's anatomy.

9. Claims 50, 54, 56, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Svetliza (6178340).

Regarding claim 50, Ilia does not teach a pedestal to which the limb support table is attached. In the same field of endeavor, Svetliza teaches a stand (#9 fig. 1B) which can be used to mount the vessel visualization device. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Svetliza to modify the teaching by Ilia for the purpose of mounting said apparatus and therefore provide mobility.

Regarding claims 54 and 65, Ilia teaches the use of a vessel visualization device but do not explicitly teach said visualization device to comprise an infrared imager. In the same field of endeavor, Svetliza discloses an infrared based vessel visualization device (col. 3 lines 3-9) and a camera (col. 5 lines 4-29). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Svetliza to modify the teaching by Ilia for the purpose of providing a more detailed visualization of the vessels in comparison to visible light.

Regarding claim 56, Ilia does not teach a vessel visualization device as being wearable over the eyes by an operator. Svetliza teaches the use of glasses or goggles

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worn by the operator (col. 3 lines 10-19). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Svetliza to modify the teaching by Ilia for the purpose of providing binocular vision and more accurate display of the placement of the needle into the vessel.

10. Claims 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Raines. Ilia does not teach the use of a storage system. In the same field of endeavor, Raines teaches a vascular examination device with a storage system comprising channels or compartments incorporated underneath, tray, racks and drawers of various sizes attached to the pedestal (col. 4 lines 56-62, col. 8 lines 17-33). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Raines to modify the teaching by Ilia to provide a storage system for the vessel visualization apparatus.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al. as set forth above, and further in view of Prier (4834802). Raines does not teach a heating pad for warming the limb. Prier discloses a heating pad for warming up limbs associated with venipuncture (abstract, col. 7 lines 23-43). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Prier to modify the teaching by Raines and Zerhusen et al. for the purpose of warming the limb and raising the vessel for better visualization during the procedure.

12. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Prier. Ilia does not teach a heated pad. Prier teaches an apparatus for warming up limbs with a heating pad (abstract, col. 7 lines 23-43). It would have therefore been

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obvious to one of ordinary skill in the art to use the teaching by Prier to modify the teaching by Ilia for the purpose of warming the limb and raising the vessel for better visualization during the procedure.

13. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Slishman (6117146). Ilia does not teach a vessel immobilizer device. In the same field of endeavor, Slishman discloses a vessel immobilizer device attached to an articulating arm member (abstract, fig. 1, col. 1 lines 50-54). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Slishman to modify the teaching by Ilia for the purpose of holding a blood vessel in place to enable proper insertion of the needle.

14. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Gion et al. (4715849). Ilia does not teach an air pump mechanism. In the same field of endeavor, Gion et al. disclose an air pump mechanism associated with drawing blood (abstract, col. 1 lines 55-68, col. 2 lines 1-15). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Gion et al. to modify the teaching by Ilia for the purpose of raising the vessel and enable better blood withdrawing procedures.

15. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ilia in view of Phoon et al. (6339732). Ilia does not teach a tape dispenser. Phoon et al. disclose a tape dispenser associated with a medication dispensing apparatus (col. 8 lines 20-42). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Phoon et al. to modify the teaching by Ilia for the purpose of

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incorporating a tape dispenser with the limb examination table for attachment of said limb to the table.

16. Claims 68, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al. as set forth above, and further in view of Svetliza. Raines discloses an apparatus for accessing the vasculature of a patient with said apparatus comprising a pedestal with a base and structural member attached to the base(col. 8 lines 17-33), a table to support a limb associated with said pedestal (col. 4 lines 35-38), a storage device comprising channels or compartments incorporated underneath, tray, racks and drawers of various sizes attached to the pedestal (col. 4 lines 56-62, col. 8 lines 17-33). Raines also teaches a vessel visualization device associated with the pedestal and limb support table (col. 4 lines 34-38). Raines further teaches a power supply source (col. 10 lines 21-24). Raines however does not teach said vessel visualization device to include a mobility means. In a similar field of endeavor, Zerhusen et al. disclose a diagnostic system capable of imaging the limbs ([0188]) with mobility means such as wheels ([0107]). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Zerhusen et al. to modify the teaching by Raines for the purpose of providing mobility to the vessel visualization apparatus. Raines and Zerhusen et al. however do not explicitly teach inserting a needle into the vessel. Svetliza teaches a vessel visualization device (col. 3 lines 3-9) for guiding a needle for puncture into a desired vessel, adjusting the position of the apparatus (col. 4 lines 25-40). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Svetliza to modify the teaching by Raines

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and Zerhusen et al. for the purpose of inserting a needle and providing for more accurate and in depth visualization of the vessels and adjusting the structure relative to the limb.

17. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Zerhusen et al. in view of Svetliza, as set forth above, and further in view of Ilia. Raines, Zerhusen et al., and Svetliza do not teach the step of securing the limb to the limb support table. Ilia teaches the use of straps to attach the limb to the table (col. 5 lines 40-55). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Ilia to modify the teaching by Raines, Zerhusen et al. and Svetliza for the purpose of securing the limb to the limb support table.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m.- 4p.m.).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*B.R.*

BR

  
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